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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,400	12/28/2001	Shinji Yamasoto	7388/72545	1864

42798 7590 06/01/2005

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EXAMINER	
PICKETT, JOHN G	

ART UNIT	PAPER NUMBER
3728	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/019,400	YAMASOTO ET AL.	
	Examiner	Art Unit	
	Gregory Pickett	3728	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Gregory Pickett*. (3)_____.

(2) *Samuel P. Burkholder*. (4)_____.

Date of Interview: *26 May 2005*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *1 and 20*.

Identification of prior art discussed: *Yuichi, Caggiano, Wilking*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Mickey Yu
Supervisory Patent Examiner
Group 3700

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Applicant's representative presented a proposed amendment (see attached fax) to include the structural limitation of the hygroscopic material extending into the peripheral areas (as shown in Figure 1 of the application). This feature is clearly not shown in Caggiano or Wilking. Yuichi addresses the bonding performance with respect to the presence of the hygroscopic material (see USPTO translation at page 3), but appears to be silent on the actual presence of the material at the periphery in its section on solving the problem. As such, the proposed amendment appears to overcome the art of record but raises a new issue that would require further search and/or consideration. Agreement was reached.

GP

Greg Pickett
Examiner
26 May 2005

Fitch, Even, Tabin & Flannery
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FACSIMILE COVER SHEET

Date: May 24, 2005

To: Examiner Pickett – Art Unit 3728 **Company:** US Patent and Trademark Office
Fax: 571-273-4560 **Tel:** 571-272-4560

Total Number of Pages (including cover sheet): 10

From: Samuel P. Burkholder **Company:** Fitch, Even, Tabin & Flannery
Fax: (202) 419-7007 **Tel:** (202) 419-7019

Message: U.S. Patent Application Number 10/019,400 to Yamasoto et al.

Please consider the attached **DRAFT** amended claims for the above-identified patent application. Please contact me at 202-419-7019 to discuss these claims.

Thank you.

Samuel P. Burkholder
Reg. No. 40,541

This transmission is being sent by Regina Martin. Please call (202) 419-7014 if there is a problem with this transmission.

Appln. No. 10/019,400
Amdt. dated May __, 2005
Reply to Office Action of November 30, 2004

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Listing of Claims:

Claim 1 (currently amended): A patch package adapted for receiving a pharmaceutical patch comprising:

(a) a first sheet consisting of:

a first moisture-permeable material layer comprising a first resin and having a moisture permeability of 40-120 g/m^2/day;

a first screen material layer that is comprised of two layers for blocking penetration of moisture and light; and

a first hygroscopic material layer located between the first moisture-permeable material layer and the first screen material layer and comprising a first resin containing 20-40 wt% of inorganic filler; and

(b) a second sheet consisting of:

a second moisture-permeable material layer comprising a second resin and having a moisture permeability of 40-120 g/m^2/day, the second moisture-permeable layer facing the first moisture-permeable material layer;

a second screen material layer that is comprised of two layers for blocking penetration of moisture and light; and

a second hygroscopic material layer located between the second moisture-permeable material layer and the second screen material layer and comprising a second resin containing 20-40 wt% of inorganic filler;

wherein the first moisture-permeable layer and the second moisture-permeable layer being directly in contact with each other at peripheral areas thereof and fixed to each other at the peripheral areas by heat sealing to form a package shape, and

at the peripheral areas, the first hygroscopic material layer and the second hygroscopic material layer are located, respectively, between the first moisture-permeable material layer and the first screen material layer, and between the second moisture-permeable material layer and the second screen material layer.

Claim 2 (previously presented): A patch package according to claim 1, wherein said first resin and the second resin are low density polyethylene, and

the two layers that form the screen material layer are a metal foil layer and a high density polyethylene layer.

Claim 3 (previously presented): A patch package according to claim 2, wherein the thickness of the hygroscopic material layer is 20-40 μm,

the thickness of the moisture-permeable material layer is 5 -15 μm,

the thickness of the high-density polyethylene layer composing the screen material layer is 10-30 μm and

the thickness of the metal foil composing the screen material layer is 5-15 μm.

Claim 4 (previously presented): A patch package according to claim 1, wherein the heat seal strength is from 1.0 kg/25 mm to 5.0 kg/25 mm.

Claim 5 (currently amended): A packaged patch comprising:

a patch having a support and a pressure-sensitive adhesive laminated on the support;

a patch package comprising;

(a) a first sheet consisting of:

a first moisture-permeable material layer comprising a first resin and having a moisture permeability of 40-120 $g/m^2/day$;

a screen material layer that is comprised of two layers for blocking penetration of moisture and light; and

a first hygroscopic material layer located between the first moisture-permeable material layer and the first screen material layer and comprising a first resin containing 20-40 wt% of inorganic filler; and

(b) a second sheet consisting of:

a second moisture-permeable material layer comprising a second resin and having a moisture permeability of 40-120 $g/m^2/day$, the second moisture-permeable layer facing the first moisture-permeable material layer;

a second screen material layer that is comprised of two layers for blocking penetration of moisture and light; and

a second hygroscopic material layer located between the second moisture-permeable material layer and the second screen material layer and comprising a second resin containing 20-40 wt% of inorganic filler;

the first moisture-permeable layer and the second moisture-permeable layer being directly in contact with each other at peripheral areas thereof and fixed to each other at the peripheral areas by heat sealing to form a package shape.

wherein the pressure-sensitive adhesive is composed mainly of a styrene-isoprene-styrene blocked copolymer, wherein the total surface area of the interior of the patch package is 1.2-10 times the effective area of said patch, and wherein said patch is in said package, and

at the peripheral areas, the first hygroscopic material layer and the second hygroscopic material layer are located, respectively, between the first moisture-permeable material layer and the first screen material layer, and between the second moisture-permeable material layer and the second screen material layer.

Claims 6 - 12 cancelled.

Claim 13 (currently amended): A patch package adapted and configured to receive a pharmaceutical patch comprising a first sheet and a second sheet, wherein each sheet consists of:

(a) a first layer being a moisture-permeable material layer, said first layer comprising a first resin and having a moisture permeability of 40-120 $g/m^2/day$;

(b) a second layer being a hygroscopic material layer that comprises a second resin containing 20-40 wt% of inorganic filler; and

(c) a third layer and a fourth layer forming a screen material layer for blocking penetration of moisture and light,

wherein the moisture-permeable layers of said first sheet and said second sheet being directly in contact with each other at peripheral areas thereof and fixed to each other at the peripheral areas by heat sealing so as to form a package shape, and

at the peripheral areas, the respective hygroscopic material layers of said first sheet and said second sheet are located between the respective

moisture-permeable material layers and screen material layers of the respective sheets.

Claim 14 (currently amended): A packaged patch comprising a pharmaceutical patch having a support and a pressure-sensitive adhesive laminated on the support within a patch package that comprises a first sheet and a second sheet, wherein each sheet consists of:

(a) a first layer being a moisture-permeable material layer, said first layer comprising a first resin and having a moisture permeability of 40-120 $g/m^2/day$;

(b) a second layer being a hygroscopic material layer that comprises a second resin containing 20-40 wt% of inorganic filler; and

(c) a third layer and a fourth layer forming a screen material layer for blocking penetration of moisture and light,

wherein the moisture-permeable layers of said first sheet and said second sheet being directly in contact with each other at peripheral areas thereof and fixed to each other at the peripheral areas by heat sealing so as to form a package shape, wherein the total surface area of the interior of the patch package is 1.2-10 times the effective area of said patch, and

at the peripheral areas, the respective hygroscopic material layers of said first sheet and said second sheet are located between the respective moisture-permeable material layers and screen material layers of the respective sheets.

Claim 15 (previously presented): A packaged patch according to claim 14, wherein the pressure sensitive adhesive is compound mainly of a styrene blocked copolymer.

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Claim 16 (previously presented): A packaged patch according to claim 14, wherein said pharmaceutical patch contains eperisone, estradiol or its derivatives, dantrolene, diclofenac sodium or scopolamine.

Claim 17 (previously presented): A packaged patch according to claim 14, wherein said pharmaceutical patch contains at least one drug selected from the group consisting of antiemetics, polakisuria agents, Ca antagonists, corticosteroids, anti-inflammatory analgesics, hypnotic analgesics, neuoleptics, antihypertensive agents, hypotensive diuretics, antibiotics, antibacterial agents, vitamins, antitussives, antidepressants, cerebral circulation ameiorants, anticancer agents, muscle relaxants, analgesics, immunoregulators, choleretic agents, smoking cessation aides, agents for diabetics, gout treatment agents, antiparkinson agents, antivertigo agents and antispasmodics.

Claim 18 (new): A patch package according to claim 1, wherein the pharmaceutical patch contains at least one drug selected from the group consisting of antiemetics, polakisuria agents, Ca antagonists, corticosteroids, anti-inflammatory analgesics, hypnotic analgesics, neuoleptics, antihypertensive agents, hypotensive diuretics, antibiotics, antibacterial agents, vitamins, antitussives, antidepressants, cerebral circulation ameiorants, anticancer agents, muscle relaxants, analgesics, immunoregulators, choleretic agents, smoking cessation aides, agents for diabetics, gout treatment agents, antiparkinson agents, antivertigo agents and antispasmodics.

Claim 19 (new): A packaged patch according to claim 13, wherein the pharmaceutical patch contains at least one drug selected from the group

consisting of antiemetics, polakisuria agents, Ca antagonists, corticosteroids, anti-inflammatory analgesics, hypnotic analgesics, neuoleptics, antihypertensive agents, hypotensive diuretics, antibiotics, antibacterial agents, vitamins, antitussives, antidepressants, cerebral circulation ameiorants, anticancer agents, muscle relaxants, analgesics, immunoregulators, cholerietic agents, smoking cessation aides, agents for diabetics, gout treatment agents, antiparkinson agents, antivertigo agents and antispasmodics.

Claim 20 (new): A patch package adapted for receiving a pharmaceutical patch comprising:

(a) a first sheet consisting of:

a first moisture-permeable material layer comprising a first resin and having a moisture permeability of 40-120 g/m^2/day;

a first screen material layer that is comprised of two layers for blocking penetration of moisture and light; and

a first hygroscopic material layer located between the first moisture-permeable material layer and the first screen material layer and comprising a first resin containing 20-40 wt% of inorganic filler; and

(b) a second sheet consisting of:

a second moisture-permeable material layer comprising a second resin and having a moisture permeability of 40-120 g/m^2/day, the second moisture-permeable layer facing the first moisture-permeable material layer;

a second screen material layer that is comprised of two layers for blocking penetration of moisture and light; and

a second hygroscopic material layer located between the second moisture-permeable material layer and the second screen material layer and comprising a second resin containing 20-40 wt% of inorganic filler;

wherein the first moisture-permeable layer and the second moisture-permeable layer being directly in contact with each other at peripheral areas thereof and sealed to each other at the peripheral areas to form a package shape, and

at the peripheral areas, the first hygroscopic material layer and the second hygroscopic material layer are located, respectively, between the first moisture-permeable material layer and the first screen material layer, and between the second moisture-permeable material layer and the second screen material layer.

Claim 21 (new): A patch package according to claim 20, wherein the first moisture-permeable layer and the second moisture-permeable layer are sealed to each other by heat sealing at the peripheral areas thereof.

Claim 22 (new): A patch package according to claim 20, wherein the pharmaceutical patch contains at least one drug selected from the group consisting of antiemetics, polakisuria agents, Ca antagonists, corticosteroids, anti-inflammatory analgesics, hypnotic analgesics, neuoleptics, antihypertensive agents, hypotensive diuretics, antibiotics, antibacterial agents, vitamins, antitussives, antidepressants, cerebral circulation ameiorants, anticancer agents, muscle relaxants, analgesics, immunoregulators, choleretic agents, smoking cessation aides, agents for

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diabetics, gout treatment agents, antiparkinson agents, antivertigo agents and antispasmodics.